K082285

510(k) SUMMARY

OCT 24 2008

Contact: Manfred Th. Plaumann

Date prepared: August 04, 2008

Trade or proprietary name: **EASY GLAZE**

Classification name: Coating, Filling Material, Resin (872.3310)

Predicate device: G-Coat K052462

Device description: **EASY GLAZE** is a nanofilled, light-curing coating with natural fluorescence for sealing surfaces. The coated surface is luminous, provides protection against discolouration and yields a natural appearance. **EASY GLAZE** can be polymerised with all light-curing dental devices.

Intended use: **EASY GLAZE** is intended for the following applications:

1. Surface sealing of provisional crowns and bridges, glass ionomer cements and definitive composite restorations.
2. Sealing the adhesive interfaces between restoration and tooth structure.
3. Protecting glass ionomer cement surfaces against the effects of moisture and dehydration immediately after placement.
4. Sealing glass ionomer cement liners/build-up restorations before taking impressions.

Technological characteristics: All of the components of **EASY GLAZE** are found in the legally marketed devices K052462 (G-Coat, the predicate device), K043168 (Biscover LV, Bisco, Inc.) K974772 (Ufi Gel SC, VOCO GmbH) and K070306 (Paint-on Polish Agent, Dentsply International, Inc.).

The prior use of all of the components of **EASY GLAZE** in legally marketed devices supports our decision that additional testing for cytotoxicity and mutagenicity as well as additional biocompatibility studies with the final formulation are not necessary.
We believe that the prior use of the components of **EASY GLAZE** in legally marketed devices and the performance data and results provided support the safety and effectiveness of **EASY GLAZE** for the intended use.

VOCO GmbH, August 04th, 2008

Manfred Th. Plaumann
Managing Board

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Thorsten Gerkensmeier
Regulatory Affairs
VOCO GmbH
Anton-Flettner-Strabe 1-3
27472 Cuxhaven
GERMANY

OCT 24 2008

Re: K082285
Trade/Device Name: EASY GLAZE
Regulation Number: 872.3310
Regulation Name: Coating Material for resin fillings
Regulatory Class: II
Product Code: EBD
Dated: August 6, 2008
Received: August 11, 2008

Dear Dr. Gerkensmeier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K082285

Device Name: EASY GLAZE

Indications for Use:

EASY GLAZE is intended for the following applications:

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Prescription Use __X__ OR **Over-The-Counter Use** _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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